

Medtronic, Inc. 21 CFR Part 11 Comments and Rationale

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Part 11 Section	Comment	Rationale
11.1(c) (Scope)	Replace section (c) with the following, "Where electronic signatures meet the requirements of this part, the agency will accept these electronic signatures when predicate rules require a signature and the decision is made to implement the signature electronically."	This revision clarifies and simplifies the scope requirements related to electronic signatures. Consistent with the FDA's Scope and Application guidance we suggest clearly referencing that predicate rules spell out when signatures are required.
11.10(e)	Change verbiage of first sentence to read "Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records <i>as required by predicate rules.</i> "	This revision would clarify and simplify the scope of audit trails. We suggest clearly referencing that predicate rules spell out when audit trails are required. With this approach it would not be necessary to introduce a risk assessment to determine when audit trails are required.
11.10(f)	Remove subsection 11.10(f).	We suggest removing this subsection since sequence control is only relevant in a small number of specific situations and should be driven by the identification of business and system requirements during the development of the computer system.
11.10(h)	Remove subsection 11.10(h).	We suggest removing this subsection since device checks are only relevant in a small number of specific situations and should be driven by the identification of business and system requirements during the development of the computer system.
11.10(i)	Change verbiage to read "Determination that persons who develop or maintain electronic record/electronic signature systems..."	We suggest removing the ", or users" portion of the sentence, since user training is already referenced in predicate rule requirements.
11.10(k)	Remove subsections (k), (k)(1) and (k)(2).	We feel this subsection is unnecessary and restates the validation requirements.
11.50(b)	Reword the subsection to read as follows, "The items identified in paragraphs (a)(1), (a)(2) and (a)(3) of this section shall be subject to the same controls as electronic records and shall be available in human readable form for the signed electronic record (such as electronic display or printout)."	This clarification allows the electronic signature information to be viewed separately from the rest of the document when it is in printed or electronic format. This would not reduce the accessibility of the information. On occasion, due to practical limitations it is not possible to include the signature on the printed report or the same application window or screen.

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11.300	Please clarify if this section is intended to apply control requirements only to identification codes / passwords used as part of electronic signatures, or if it is meant to include identification codes / passwords used to access systems.	While we understand that these requirements are located in a section of the regulation pertaining to electronic signatures, enforcement of such requirements as password aging 11.300(b) have been applied more broadly.